

✓ Page 6, line 6, please remove "44" and insert -- (not shown) --.

✓ Page 6, line 25, please remove "33" and insert -- (not shown) --.

### REMARKS

Originally, 21 claims were filed with this application.

No new matter is added by way of this Amendment. Examination, reconsideration, and allowance of the claims are respectfully requested.

### REJECTION UNDER 35 U.S.C. §103

Claims 1-7 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Benedick (US 5,692,246), in view of Lugin (US 4,683,601), along with Gerhard (US 5,843,008). Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable as applied to claim 1 above, and further in view of Blackburn (US 5,363,523). Claims 10-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over references as applied to claim 1 above, and further in view of Lebold (US 3,889,684). Claims 14-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Blackburn (US 5,363,523). Claims 18-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Blackburn (US 5,363,523) in view of Lebold (US 3,889,684). Claim 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over the references as applied to claim 20, and further in view of Lugin (US 4,683,601). The rejection of the claims is respectfully traversed.

### Background

As noted in the patent application as filed, a main objective of this invention is to provide method and device for applying pressure to the chest of post chest surgery patients, which includes a casing for a pillow to be inserted, a membrane where a warming or cooling device could be placed, as well as a place to rest ones arm so that the pectoralis muscles remain relaxed, and lastly also comprises gripping handles, so that the pillow can exert pressure on the chest. [Bamdad et al application, pgs. 6-8]

Benedick et al. ('246')

Benedick describes a chest pillow or chest protector, which utilizes a set of two straps which go around the shoulders of the patient, whereby the pillow can then be hugged by the patient when a coughing spasm begins. ['246', Abstract, lines 5-8]. Combination with Gerhard (US 5,843,008) or Lakin (US 4,683,601) does not produce the Applicant's invention as described. Gerhard teaches a medical device with gripping handles, however to use the device the patient must crisscross their arms across their chest, pull the winged portions across their back, causing the device to constrict around the patient. ['008', Col. 6, lines 52-58]. Lastly, Lakin teaches a device which has a sleeve for receiving the patients hands. ['601', Col. 4, lines 13-15]. Although Applicant uses the same general design of a medical pillow, Applicant's invention has structural elements that are neither taught nor suggested by these references.

Blackburn ('523')

Blackburn teaches a medical pillow with a pocket for an insertion of a weight. ['372, Abstract, lines 7-8]. Further, Blackburn does not teach or suggest the use of any strap, sleeve, or

gripping handle. While Lugin teaches a device for receiving the patients arms, there no suggestion or teaching of a strap, sleeve, or gripping handle. Furthermore, Applicant's invention performs various functions and has structural elements that are neither taught nor suggested by this reference.

Lebold ('684')

Lebold teaches a membrane which can be filled with a warming or cooling pack. Although it has straps to position the pack over a large body area, there is no continuous strap. Nor is there any suggestion to combine a medical pillow with a heating or cooling apparatus in either Lebold or Blackburn. Applicant's invention performs various functions and has structural elements that are neither taught nor suggested by this reference.

The Present Invention

The essence of the claimed invention is a medical pillow which comprises casing substantially in the form of a pillow, a membrane layer forming a sleeve for receiving of hands and forearms of the patient, a contiguous strap to go around the patient's neck, and gripping handles. [Patent Application, p. 4, ln. 1-12.] An important objective of the invention is to reduce the movement and dehision of the sternum, by applying pressure to the whole of the chest area, remaining readily accessible to the patients without having the patients move their arms for placement of the pillow, and using the gripping handles. [Patent Application, p. 4, lines 16-28.] Another important objective of the invention is to decrease the healing time of the sternum bone after open heart and chest surgeries. [Patent Application, p. 4, lines 29-30.]

DIFFERENCE BETWEEN CITED ART AND APPLICANT'S INVENTION

Benedick's Medical Pillow v. Applicant's Method and Device

It is fundamental to understand the purposes and motivations of Benedick in view of others and the purpose of the present invention in order to understand the difference in functionality and the structural differences between Benedick's and others from the present invention.

Benedick, when combined with Lagin produces a medical pillow which has a set of straps which go around the shoulders of the person and has a sleeve for the insertion of the patient's arms. However, there is no mention of grips or gripping handles with which to apply pressure, nor of a contiguous strap to go around the patient's neck. Examiner also uses Benedick in combination with Gerhard which would produce a medical pillow which has a set of straps which go around the shoulders of the person and has gripping handles. However, in each design of Gerhard the gripping handles must be pulled either out and away from the person's body or downward, both of which would cause the patient's incision to open up with the movement of the arms. However, Applicant's invention in claim 1 sets out three criteria, which are not contained in any combination of two of the above patents.

1. b. a membrane layer...forming a sleeve for receiving of the hands and forearms of a patient,
- c. a contiguous strap...for attachment around the neck of the patient, and
- d. a gripping handle, for the patient to grab with their hands. [Patent Application, p. 11, lines 23-22.]

At no time is the patient required to move their arms to apply pressure, or quickly reach for a

pillow. Furthermore, the idea of the sleeve and gripping handles is to allow the patient to apply pressure to the pillow without using their pectoralis muscles, thereby decreasing dehesis.

[Patent Application, p. 4, ln. 25-28.]

Because claims 2-13 depend on claim 1, and the patents above do not teach every limitation, claims 1-13 should be allowed.

Blackburn's Method v. Applicant's Method for Reducing Dehesis

Blackburn teaches a method of insertion of a weight into a pocket, for increasing the gravitational pull of the pillow when it is being squeezed. However, in Blackburn there is no mention of a strap or gripping handles, it is merely hugged to the patient's chest. The method of use in the description is only "with the hands folded as shown." [Blackburn, '523, col. 2, ln. 61-62.] Figure 2 shows the patient crossing his arms across his upper chest, forcing the pectoralis muscles to do most of the work. Further, there is no mention of reducing movement or dehension of the sternum, only of increasing comfort to the patient. [Blackburn, '523, col. 2, ln. 1-2.] Lastly, there is no mention of how the pillow is supported.

Applicant's invention describes a method of reducing movement and dehesis of the sternum and chest incision. The method comprises placing pressure on the device, **supported by the neck, by gripping the handles** and exerting pressure on the device. [Patent Application, p. 13, ln. 3-4.] As described in the specification, it is desirable to have the medical pillow easily accessible, so that the patient does not have to reach for the pillow, foreseeably causing dehesis when the patient reaches for the pillow. Further explained in claim 16, Applicant's invention prescribes for the "pressure to be applied across the chest surface area...by pressing down the

elbows of the patient towards the chest area using the latismus dorsi muscles.” [Patent application, p. 13, ln. 9-13] This is substantially different from Blackburn which when the pillow is used would use the pectoralis muscles, causing dehesis, which is precisely what Applicant seeks to avoid.

Claims 18 and 19 are also rejected under Blackburn in view of Lebold. However, as discussed above, Blackburn does not teach or suggest the elements of independent claim 14. Even with the addition of Lebold, which consists of a heating or cooling pack, **the method of application of force** is still not described.

Claims 15-19 are all dependent on claim 14, and as explained above, claim 14 contains a method not described in Blackburn and should be allowed.

Blackburn is also cited in the rejection of claim 20. The arguments for allowance are substantially the same as above. Applicant’s claim 20 is a method claim for expediting fusion of the sternum, whereby a device is secured about the neck of the patient, and is then hugged to the chest by crossing the forearms and gripping the handles, whereby pressure is applied to the device.

Claim 21 is dependent on claim 20, and is rejected over Blackburn in view of Lakin. As explained above Blackburn does not substantially teach or suggest **the method of use** explained in Applicant’s invention. Addition of a sleeve to hold the hands, taught in Lakin **does not result in a method** whereby a device is supported by the neck, hugging the device by crossing the forearms and gripping the gripping handles, where the forearms and hands are supported by a sleeve.

The legal Conclusion of Obviousness

Once the relevant inquiries of Graham v. Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1967) have been completed, the patent Office must determine whether they support a conclusion of prima facie obviousness. Prime facie are not supported merely because the references could have been combined. In re Chicago Rawhids Mhg. Co., 223 U.S.P.Q. 351. In addition, the Patent Office must also address the critical determination of whether the prior art suggests the proposed combination. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. Carella v. Straight Archery, 231 U.S.P.Q. 644 (Fed. Cir. 1986). “Something in the prior art must provide a motivation whereby one of ordinary skill would be led to do that which the applicant has done.” In re Dillon, 13 U.S.P.Q. 2d 1337, 1341. Combinations that do not teach or suggest the claimed invention cannot support a 103 rejection. In re Geiger, 2 U.S.P.Q. 2d 1278 (Fed. Cir. 1987)

As was noted above, the Patent Office has not pointed out a combination of only two patents that teach all of the limitations. Indeed individually or in combination, neither Benedick with Lugin and Gerhard nor Blackburn with Lugin and Lebold teach or suggest all of the claimed elements of Applicant’s independent claims. Therefore, the rejection under 35 U.S.C. 103 must fail.

THERE IS NO OBVIOUSNESS UNDER 35 U.S.C. § 103Applicant’s Claimed Invention

Independent claim 1 clearly defines the claimed subject matter. In particular, claim 1 recites that the device has,

- “b. a membrane layer...forming a sleeve for receiving the hands and forearms of a patient,
- c. a contiguous strap attached to the top corners of the back side for attachment of the casing around the neck of the patient for immediate proximity...to the patient’s chest incision area, and
- d. a gripping handles for the patient to grab with their hands.”

As explained in more detail below, the language clearly requires that the device be hung from the neck of the patient, and a sleeve where a patient may rest both his hands and forearms, in near proximity to the gripping handles. Clearly, as has been noted in the specification as filed, only this combination has the desired effect of decreasing dehesis and expediting fusion of a cut sternum.

Independent claim 14 also clearly defines the method of the claimed subject matter. In particular, claim 14 recites that the method of the use is,

- “a. placing a pressure device on the chest area of the patient...,
- b. supporting the device around the neck of the patient, for positioning the pressure device in the immediate proximity of the patient’s chest incision area,
- c. hugging the pressure device by crossing the forearms over the pressure device and gripping the gripping handles....,
- d. exerting pressure on the pressure device for reducing the movement and dehesis of the sternum.”

This language clearly requires that the patient use the medical pillow by grasping the gripping handles where the device is supported by the neck. Only use of the medical pillow in this fashion will have the desired effect of preventing dehesis of the cut sternum.



Suggestion to Combine Must Come From the Prior Art

A prime facie case of obviousness requires that at least one of the references provide some motivation or suggestion to combine the elements of the separate references to derive Applicant's invention. There must be some suggestion supporting the combination other than hindsight gleaned from the invention itself. Uniroyal, Inc. v. Rudkin Wiley Corp., 837 F.2d 1044, 1051, 5 U.S.P.O. 2d 1434, 1438 (Fed. Cir.) cert. Denied, 488 U.S. 825 (1988).

To establish a prima facie case, the Patent Office may not rely on unsupported assertions about the level of ordinary skill in the art or bare conclusions that one of ordinary skill in the art could apply such skill to obtain the claimed invention. In re Rijckaert, F. 3d, No. 93-1206, Slip Op. At 5 [28 U.S.P.Q. 2d 1955] (Fed. Cir. Nov. 23, 1993)

The Patent Office has cited no particular section in Benedick, Blackburn, or Lebold which teaches or suggests the particular combination of elements claimed by Applicant, or the desirability of such a combination. There is no express or implied statement in Benedick, Blackburn, or Lebold that teaches or recognizes that heating or cooling of the chest area after chest surgery is beneficial or will increase the comfort of the patient.

The strongest rationale for combining references is a recognition that some advantage or expected beneficial result would have been produced for the proposed combination. In re Sernacker, 217 U.S.P.Q. 1 (Fed. Cir. 1983). The recognition may be an express statement in a reference, or an implication that can be drawn from one or more references. The Patent Office has failed to cite an explicit statement, or implication that can be drawn from particular statements in either Benedick or Blackburn that is the basis for any suggestion or motivation to

combine the references with Lebold.

The Patent Office May Not Rely On Unsupported Assertions About The Level Of Ordinary Skill In The Art

To establish a prima facie case of obviousness, the Patent Office may not rely on unsupported assertions about the level of ordinary skill in the art or bare conclusions that one of ordinary skill could apply such skill to obtain the claimed invention. In re Rijckaert, F. 3d, No. 93-1206, Slip Op. At 5, 28 U.S.P.Q. 2d 1955. Here, Applicant's invention should not be rejected as "obvious to one of ordinary skill in the art at the time the invention was made." Applicant's invention provides real benefits and unobvious properties not discussed or taught by others as discussed below.

Unobvious Properties

The question asked by section 103 is whether the "subject matter as a whole" would have been obvious at the time of the invention. The subject matter as a whole has been interpreted by the courts to include not only the express structure or steps recited in the claims, but also any properties, results, or advantages produced by the claimed subject matter. In re Antonie, 195 U.S.P.Q. 6, 8 (CCPA 1977)

Even if it is believed that there is suggestion or motivation to combine the references to arrive at applicant's claimed invention, evidence demonstrating that Applicant's invention produced properties not possessed by the prior art must be considered by the Patent Office. Although no beneficial effect is required for patentability of an invention, Applicant's elimination of the reliance on the pectoralis muscles to apply pressure to the chest area an unobvious benefit

that provides numerous beneficial results.

In rejection of claim 14, examiner states that one having ordinary skill in the art would have understood that the side of the casing are gripped by the patient's hands. However, Figure 2 of Blackburn shows the hands flat against the medical pillow in the middle of the chest. Applicant's invention provides for an actual place to put ones fingers, so that they actually curl around and into of the pillow. [Patent Application, Figure 3 and 4.] Further, in Applicant's invention, the arms actually completely cross the midsection of the patient's body. [Patent Application, Figure 3 and 4.]

In view of all of the foregoing reasons, removal of the rejection under 35 U.S.C., Section 103 is respectfully requested and Applicant believes that claim 1 as amended is in condition for allowance.

#### DEPENDENT CLAIMS

All other dependent claims are dependent upon claims 1, 14, and 21. These claims are therefore, in condition for allowance. Allowance of these claims is solicited.

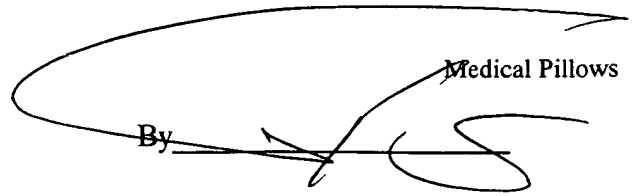
#### CONCLUSION

The application as amended, and for the reasons detailed above, is believed to place the present application in condition for allowance and an early notice of allowance is respectfully requested. Should the Examiner have any questions regarding the above amendments, the Examiner is request to telephone Applicant's representative at the number listed below.

12-23-03

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Medical Pillows  
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